IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

UNITED STATES OF AMERICA ex rel. Braeden M. Hearrell,	§	
	§	
Relator,	§	
	§	
v.	§	CIVIL ACTION NO. 2:21-CV-00204-JRG
	§	
ALLERGAN, INC.,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Allergan Inc.'s ("Allergan") Motion to Dismiss Relator's Fourth Amended Complaint (the "Motion") Pursuant to Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 57.) Having considered the Motion and its briefing, the Court finds that it should be and hereby is **GRANTED-IN-PART** and **DENIED-IN-PART** for the reasons set forth herein.

I. PROCEDURAL HISTORY AND POSTURE

On June 7, 2021, Relator Braeden Hearrell ("Relator") filed a complaint on behalf of the United States against Allergan alleging that Allergan violated the False Claims Act ("FCA"). (Dkt. No. 2.) The United States declined to intervene. (Dkt. No. 13.) Relator amended his complaint on March 16, 2023. (Dkt. No. 15.) On May 22, 2023, Allergan moved to dismiss the First Amended Complaint pursuant to Federal Rule of Civil Procedure 12(b)(6). (Dkt. No. 26.) In response, Relator filed a Second Amended Complaint, mooting Allergan's pending Motion to Dismiss. (Dkt. No. 40; Dkt. No. 46.) On August 25, 2023, Allergan filed its Motion to Dismiss Relator's Second Amended Complaint. (Dkt. No. 47.) In response, Relator filed a Third Amended Complaint and a short responsive brief addressing Allergan's Motion to Dismiss. (Dkt. No. 50;

Dkt. No. 51.) Allergan's reply brief followed shortly thereafter. (Dkt. No. 52.) On November 7, 2023, Relator filed a Fourth Amended Complaint. (Dkt. No. 53.) On November 11, 2023, Allergan filed its Motion to Dismiss Allergan's Fourth Amended Complaint and asked the Court to apply the parties' existing briefing to Relator's Fourth Amended Complaint. (Dkt. No. 57.) That motion is now before the Court.

II. LEGAL STANDARD

Under the Federal Rules of Civil Procedure, a complaint must include "a short and plain statement of the claim showing that the pleader is entitled to relief." Fed. R. Civ. P. 8(a)(2). A Court can dismiss a complaint that fails to meet this standard. FED. R. CIV. P. 12(b)(6). To survive dismissal at the pleading stage, a complaint must state enough facts such that the claim to relief is plausible on its face. *Thompson v. City of Waco*, 764 F.3d 500, 502 (5th Cir. 2014) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the plaintiff pleads enough facts to allow the Court to draw a reasonable inference that the defendant is liable for the misconduct alleged. *Id.* (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)). The Court accepts well-pleaded facts as true and views all facts in the light most favorable to the plaintiff but is not required to accept the plaintiff's legal conclusions as true. *Id.* "[A] complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations." *Twombly,* 550 U.S. at 555.

In the Fifth Circuit, motions to dismiss under Rule 12(b)(6) are viewed with disfavor and are rarely granted. *Lormand v. US Unwired, Inc.*, 565 F.3d 228, 232 (5th Cir. 2009); *Lowrey v. Texas A&M Univ. Sys.*, 117 F.3d 242, 247 (5th Cir. 1997). "The court may consider 'the complaint, any documents attached to the complaint, and any documents attached to the motion to dismiss that are central to the claim and referenced by the complaint.'" *Script Sec. Sols. L.L.C. v.*

Amazon.com, Inc., 170 F. Supp. 3d 928, 935 (E.D. Tex. 2016) (quoting *Lone Star Fund V (U.S.) L.P. v. Barclays Bank PLC*, 594 F.3d 383, 387 (5th Cir. 2010)).

Rule 9(b) imposes a heightened pleading standard on fraud claims, including *qui tam* claims brought under the FCA. *See* FED. R. CIV. P. 9(b); *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 185 (5th Cir. 2009). Rule 9(b) states: "In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." FED. R. CIV. P. 9(b). An FCA claim "may" satisfy Rule 9(b) if the complaint "alleg[es] particular details of a scheme to submit false claims" and those details are "paired with reliable indicia that lead to a strong inference that claims were actually submitted." *U.S. ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 190 (5th Cir. 2009). A dismissal for failure to plead fraud with particularity under Rule 9(b) is treated as a dismissal for failure to state a claim under Rule 12(b)(6). *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 901 (5th Cir. 1997).

III. DISCUSSION

Relator pursues two distinct theories under the False Claims Act ("FCA"): (1) that Allergan's off-label promotion of Botox for pediatric migraine therapy violates the FCA; and (2) that Allergan paid illegal kickbacks to physicians in violation of the Anti-Kickback Statute ("AKS"). (Dkt. No. 53 at 10-16.) Relator also alleges a violation of the FCA based on the Stark Act. (*Id.* at 46-48.) In its Motion, Allergan seeks dismissal of all counts in Plaintiff's Complaint. (*See* Dkt. No. 47.) The Court addresses each of Allergan's arguments in turn.

A. The Public Disclosure Bar

Allergan asserts that the public disclosure bar precludes Relator as to all its claims and theories under the FCA. The FCA's public disclosure bar precludes a relator from pursuing an action "if substantially the same allegations or transactions as alleged in the action or claim were publicly disclosed," unless the relator is an "original source" of the allegations. 31 U.S.C. §

3730(e)(4)(A). "The critical elements have been sufficiently disclosed if the disclosures, taken together, would enable the government to draw an inference of fraud." *U.S. ex rel. Health v. Dallas/Fort Worth Int'l Airport Bd.*, 2004 WL 1197483, at *5 (N.D. Tex. May 28, 2004). "The guiding query is whether one could have produced the substance of the complaint merely by synthesizing the public disclosures' description of a scheme." *Little v. Shell Expl. & Prod. Co.*, 690 F.3d 282, 293 (5th Cir. 2012) (internal citations omitted). "In order to disclose the fraudulent transaction publicly, the combination of X and Y must be revealed, from which readers or listeners may infer Z, i.e., the conclusion that fraud has been committed." *U.S. ex rel. Colquitt v. Abbott Lab'ys*, 864 F. Supp. 2d 499, 539 (N.D. Tex. 2012), *aff'd sub nom. U.S. ex rel. Colquitt v. Abbott Lab'ys*, 858 F.3d 365 (5th Cir. 2017).

Allergan specifically argues that the public disclosure bar of the FCA precludes Relator from pursuing his claims because the essential elements of the alleged fraud—(a) off-label use of Botox for pediatric migraine therapy and (b) Allergan's off-label "promotional" activities—were already publicly disclosed. (Dkt. No. 47 at 6-12.) Allergan noted that the off-label use of Botox for pediatric migraine therapy was widely reported in news articles. (*Id.* at 8-9.) In support, Allergan furnishes, among other things, a public 2018 article about Relator's doctor, Dr. Tonia Sabo, describing the use of Botox to treat pediatric migraines. (*Id.* at 8.) Allergan further argues that its alleged "promotional activities" were also publicly disclosed through lawsuits and news media. (*Id.* at 9-12.)

In response, Relator argues that he has made allegations about Allergan's promotional schemes for off-label use of Botox specifically for pediatric migraine treatment—a different off-label use than was shown in the prior disclosures. (Dkt. No. 51 at 4.)

Allergan responds that the documents do not need to allege the promotional "scheme" and the "same off-label use together in one place." (Dkt. No. 52 at 3.) Rather, "the repeated disclosure of each essential element during the relevant period more than suffices." (*Id.*)

Having considered the above arguments, the Court finds that Relator's fraud claims were not publicly disclosed and are therefore not barred by the public disclosure bar. While Allergan identified public documents showing off-label use of Botox, Allergan does not show any public documents showing its "promotional" activities concerning off-label use of Botox for treatment of pediatric migraines, specifically.[1] The Court finds that the cited disclosures, when taken together, would not have enabled an ordinary reader or listener to draw an inference of fraud. In light of this, the Court need not reach the "original source" issue, which applies only if the fraud claims were publicly disclosed.

Accordingly, the Court finds that Allergan's Motion as to the FCA's public disclosure bar should be and hereby is **DENIED**.

B. Relator's Claims Under the False Claims Act

The False Claims Act ("FCA") authorizes private parties, called "relators," to file suit on behalf of the United States against anyone submitting false claims to the government. 31 U.S.C. §§ 3729-3730. Claims brought under the FCA must comply with Rule 9(b). *U.S. ex rel. Thompson v. Columbia/HCA Healthcare Corp.*, 125 F.3d 899, 903 (5th Cir. 1997). A relator must satisfy four elements in order to state a cause of action under the FCA: (1) a false statement or fraudulent course of conduct; (2) that was made or carried out with the requisite scienter; (3) that was material; and (4) that caused the government to pay out money (i.e., that involved a claim). *U.S. ex rel. Spicer v. Westbrook*, 751 F.3d 354, 365 (5th Cir. 2014).

[1] Indeed, Allegan admits that the disclosed "promotional" activities concerned different off-label uses of Botox. (Dkt. No. 47 at 10.)

A claim or record is false if the submitting party provides inaccurate information or falsely certifies compliance with a statute or regulation. *U.S. ex rel. Ruscher v. Omnicare, Inc.*, 663 F. App'x 368, 373 (5th Cir. 2016). Materiality turns on whether the government would pay the claim or not if it knew of the claimant's violation. *U.S. ex rel. Patel v. Cath. Health Initiatives*, 792 F. App'x 296, 301 (5th Cir. 2019). To plead scienter, Relator must allege facts supporting an inference that the alleged fraud amounts to "more than innocent mistake or negligence." *United States ex rel. Jacobs v. Walgreen Co.*, No. 21-20463, 2022 WL 613160, at *1 (5th Cir. Mar. 2, 2022), *cert. denied sub nom. Jacobs v. Walgreen Co.*, 143 S. Ct. 104, 214 L. Ed. 2d 23 (2022).

Relator pursues a theory that Allergan's alleged off-label promotion of Botox for pediatric migraine treatment violates the FCA. (Dkt. No. 58 at 13-20, 23-30.) The Court addresses each element under the FCA as to such claim in turn.

i. Falsity

Allergan argues that off-label prescriptions of Botox are not false statements because they do not contain inaccurate information. (Dkt. No. 47 at 17-22.) Allergan notes that the FDA permits physicians to prescribe drugs for off-label uses, and that neither Medicare nor Medicaid categorically prohibits reimbursement of off-label prescriptions. (*Id.* at 18-19.)

Allergan further argues that Relator pleads no facts relating to a false certification theory because a provider who certifies compliance with Medicare rules does not make false statements by submitting a claim for an off-label prescription. (*Id.* at 20.) According to Allergan, the falsity of a claim under the false certification theory turns on whether the claim is reimbursable under Medicaid or Medicare, which turns on whether the treatment was "reasonable and necessary." (Dkt. No. 61 at 1-2.) Allergan argues that Relator expressly concedes that his claims are not based upon the reasonableness and necessity of using Botox for treatment of pediatric migraine. (*Id.* at 2.)

In addition, Allergan argues that Relator cannot plead falsity by arguing that off-label marketing violates separate FDA regulations and statutes because "the FCA is not a general enforcement device for federal statutes and regulations." (Dkt. No. 47 at 20.)

In response, Relator argues that Allergan violates the Federal Food, Drug, and Cosmetic Act (FDCA) and the Public Health Service Act (PHSA) by marketing and promoting a drug for an off-label use that the FDA has not approved. (Dkt. No. 58 at 13.) Relator also argues that "once a violation of the AKS has been alleged, the first element of the FCA, falsity, has been met." (*Id.* at 16.)

The Court finds that Relator has not adequately pled facts supporting the inference that Allergan made a false statement or falsely certified compliance with a statute or regulation. Relator alleges no facts showing that an off-label prescription is factually false or misleading. Nor has Relater sufficiently alleged that Allergan falsely certified compliance with Medicaid or Medicare by submitting a claim for a treatment that was not "reasonable and necessary." Indeed, Relator expressly concedes in his Response that his claims "are not based upon the reasonableness and necessity of treatment." (Dkt. No. 58 at 18.)

To show falsity, Relator alleges that Allergan violated multiple federal laws, including the FDCA, the PHSA, and the Anti-Kickback Statute ("AKS"). However, under 5th Circuit precedent, Relator's allegations that Allergan violated federal statutes do not suffice to plead falsity unless Allergan also certified compliance as to those statutes. The Fourth Amended Complaint falls short in this respect. Moreover, Relator cites no case law suggesting that merely pleading a violation under the AKS automatically suffices to plead falsity for a theory that does not otherwise rely upon the AKS. The Court is not convinced that Relator can rely on the AKS for a showing of falsity as to both his AKS-based FCA theory and his non-AKS FCA theory.

ii. Materiality

Allergan argues that Relator fails to allege that the government would not have paid the claims had it known of the claimant's violation, or that the government consistently refuses to pay claims for off-label Botox. (Dkt. No. 47 at 25.) Relator responds that violations of the AKS are "inherently material" under the FCA. (Dkt. No. 58 at 25.)

The Court finds that Relator has not adequately pled the materiality element. As discussed above, the Court does not agree that merely pleading a violation under the AKS suffices to plead materiality for a theory that does not otherwise rely upon the AKS. Beyond the bare AKS allegations, Relator proffers no facts supporting an inference that prescribing off-label is material to Medicare's or Medicaid's payment decisions under the FCA.

iii. Scienter

Allergan argues that Relator's allegations do not even show negligence, let alone an inference of fraud. (Dkt. No. 47 at 28.) In particular, Allergan argues that its knowledge and promotion of off-label use do not show knowledge of anything unlawful. (*Id.*)

In response, Relator argues that 48 claims involving the use of Botox for pediatric migraine were submitted to the government for payment, and that Allergan knew these claims were false because each claim was "incorrectly certified as being complaint with the AKS." (Dkt. No. 58 at 29.)

Consistent with its earlier findings, the Court finds that Relator does not adequately allege scienter. Relator again attempts to use his AKS allegations to bolster a theory that does not otherwise rely upon the AKS. In the Court's view, that is insufficient. Relator otherwise alleges no facts suggesting that the alleged fraud amounts to more than innocent mistake or negligence.

Having considered the briefing and the Fourth Amended Complaint, the Court finds that Allergan's Motion as to Relator's off-label promotion theory under the FCA should be and hereby

is **GRANTED WITHOUT PREJUDICE**. It is further **ORDERED** that Relator is granted leave to refile an amended pleading as to his off-label promotion FCA theory within fourteen (14) days hereof.

C. Relator's Claims Under the Anti-Kickback Statute

The Anti-Kickback Statute ("AKS") prohibits "knowingly and willfully" offering or paying "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program." 42 U.S.C.A § 1320(b)(2). "A violation of the AKS can serve as the basis for a FCA claim when the Government has conditioned payment of a claim upon the claimant's certification of compliance with the statute, and the claimant falsely certifies compliance." *U.S. ex rel. Nunnally v. W. Calcasieu Cameron Hosp.*, 519 F. App'x 890, 893 (5th Cir. 2013). When brought under an FCA claim, the elements of the AKS violation must also be pleaded with particularity under Rule 9(b). *Id.* at 894. To state an AKS-based FCA claim, the claimant must "provide reliable indicia that there was a kickback provided in turn for the referral of patients." *Id.* at 894.

In addition to his off-label promotion FCA theory, Relator also pursues a theory that Allergan's violation of the AKS serves as the basis for an FCA claim. (Dkt. No. 58 at 22-23.)

Allergan argues that Relator alleges no facts supporting the inference that Allergan paid remuneration within the meaning of the AKS beyond his own ipse dixit. (Dkt. No. 47 at 23.) Specifically, Allergan argues that Relator provides no facts about the alleged kickback scheme as to either the Key Opinion Leaders ("KOLs") hired by Allergan or the recruited physicians to whom

the KOLs promoted Botox.[2] (Dkt. No. 61 at 3-5.) As to the KOLs, Allergan notes that it is not illegal to hire KOLs and have them promote the use of Botox to other doctors. (*Id.* at 3.) As to the recruited physicians, Allergan argues that mere attendance at a group dinner is not a "kickback" under the AKS. (*Id.* at 4.) Furthermore, Allergan argues that Relator did not offer any factual link between the dinners and the 48 claims that Relator alleges were submitted to federal payers between 2015 and 2019. (*Id.* at 5-6.) Finally, Allergan argues that Relator did not meet the AKS scienter requirement by alleging facts showing that Allergan "intended to pay improper remuneration and also intended that the resulting false claims be submitted for reimbursement to the government." (Dkt. No. 47 at 29.)

Relator responds that Allergan knowingly hired KOLs to recruit physicians to participate in Allergan's promotion of Botox for pediatric migraine therapy. (Dkt. No. 58 at 22.) Relator further argues that Allergan knowingly paid cash payments to KOLs in exchange for referrals to pediatric specialists who would, in turn, administer Botox for treatment of pediatric migraines. (*Id.*)

Having considered the Fourth Amended Complaint and the above arguments, the Court finds that Relator has sufficiently pled an AKS-based FCA claim. In the Fourth Amended Complaint, Relator alleges that Allergan knowingly made "direct cash payments to KOLs in exchange for referrals to pediatric specialists who would, in turn, administer Botox for chronic migraines to minors and seek payment from Medicaid-funded medical services." (Dkt. No. 53 at 15.) Relator further alleges that KOLs were "given cash payments in exchange for promoting the use of Botox at lavish promotional dinners that were also attended by . . . pediatric specialists." (*Id.* at 41.) In addition, Relator alleges that Allergan paid illegal kickbacks to physicians "in the

[2] Relator alleged in the Fourth Amended Complaint that Allergan hires KOLs to recruit physicians to participate in Allergan's promotional activities, such as "lavish" dinners and injection training events. (Dkt. No. 53 at 5-10.)

form of cash, travel, lodging, and meals," (including the "lavish promotional dinners" discussed above) as an inducement to "prescribe Botox to patients for both off-label and approved indications." (*Id.* at 14.) Relator also alleges that Allergan certified compliance with "all Medicare laws, regulations, and program instructions," including "the Federal Anti-Kickback Statute." (*Id.* at 34.) Therefore, the Court finds that the Fourth Amended Complaint provides adequate factual content supporting its AKS-based FCA claim and gives reasonable notice as to Relator's claims against Allergan. Accordingly, the Court finds that Allergan's Motion as to Relator's AKS-based FCA claim should be and hereby is **DENIED**.

D. Relator's Claims Under the Stark Act

The Fourth Amended Complaint includes brief allegations relating to the Stark Act. (Dkt. No. 53 at 46-48.) The Stark Act prohibits a physician with a "financial relationship" with an entity from referring a patient to the entity "for the furnishing of designated health services." 42 U.S.C. § 1395nn(a)(1).

Allergan argues that the Stark Act does not contemplate the alleged referrals in the Fourth Amended Complaint—the KOLs referring pediatric specialists to attend Allergan's marketing scheme. (Dkt. No. 52 at 8.) Allergan further argues that Relator has not alleged that anyone made a referral "for the furnishing of health services." (Dkt. No. 52 at 8.) Relator does not respond to Allergan's arguments in his briefing.

The Court finds that the Relator fails to state a claim under the FCA based on the Stark Act. Relator alleges no financial relationship between any KOL, any physician, and any entity that provides "health services." Accordingly, Allergan's Motion as to Relator's Stark Act claim is **GRANTED WITHOUT PREJUDICE**. It is further **ORDERED** that Relator is granted leave to refile an amended pleading as to Allergan's Stark Act violation within fourteen (14) days hereof.

V. CONCLUSION

For the foregoing reasons, Allergan's Motion (Dkt. No. 57) is **GRANTED-IN-PART** and **DENIED-IN-PART**. As noted above, Relator is granted leave to refile an amended pleading as to his off-label promotion FCA theory and Allergan's Stark Act violation within fourteen (14) days hereof.

So ORDERED and SIGNED this 18th day of April, 2024.

RODNEY GILSTRAP
UNITED STATES DISTRICT JUDGE